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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/067,503	02/07/2002	Benoit Salomon	3665-21	7318

7590 09/11/2003

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EXAMINER	
WILSON, MICHAEL C	
ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 09/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/067,503	SALOMON ET AL.
	Examiner	Art Unit
	Michael C. Wilson	1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-18* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-14 and 16, drawn to a method of treating an immune disease using non-genetically altered T-cells that suppress a pathological immune response, classified in class 424, subclass 93.7.

II. Claims 1-16, drawn to a method of treating an immune disease using genetically altered T-cells that suppress a pathological immune response, classified in class 424, subclass 93.2.

III. Claim 17, drawn to a composition comprising a genetically modified human immunoregulatory T-cell, classified in class 435, subclass 372.3.

IV. Claim 18, drawn to a method of producing non-genetically altered human immunoregulatory T-cells, classified in class 435, subclass 386.

V. Claim 18, drawn to a method of producing genetically altered human immunoregulatory T-cells, classified in class 435, subclass 455.

The inventions are distinct, each from the other because of the following reasons:

Groups I and II are patentably distinct because they have different modes of operation. Non-genetically modified cells suppress the pathological immune response in Group I, while the genetically modified cells in Group II deliver proteins not produced by the T-cells that suppress the pathological immune response. The protocols and reagents required for genetically modified cells are materially distinct and separate than

those required for non-genetically modified cells. The method of using non-genetically modified cells does not require the method of using genetically modified cells and the method of using the genetically modified cells does not require the method of using the non-genetically modified cells.

Groups I and III are patentably distinct because administering non-genetically modified cells is used to suppress the pathological immune response while the genetically modified cells can be used to express proteins not produced by the cells. The protocols and reagents required for treating disease using non-genetically modified cells and for making/using genetically modified cells are materially distinct and separate. The method of using non-genetically modified cells do not require the genetically modified cells and the genetically modified cells do not require the method of using non-genetically modified cells.

Groups I and IV are patentably distinct because the purpose of Group I is to treat disease while the purpose of Group IV is to produce non-genetically modified human immunoregulatory T-cells. The protocols and reagents for treating disease and for producing T-cells are materially distinct and separate. The method of treating disease does not require the method of producing T-cells and the method of producing T-cells does not require the method of treating disease.

Groups I and V are patentably distinct because the purpose of Group I is to treat disease while the purpose of Group V is to produce genetically modified human immunoregulatory T-cells. The protocols and reagents for treating disease and for producing T-cells are materially distinct and separate. The method of treating disease

does not require the method of producing T-cells and the method of producing T-cells does not require the method of treating disease.

Groups II and III are patentably distinct because administering genetically modified immunoregulatory T-cells is used to suppress the pathological immune response while the genetically modified human immunoregulatory T-cells can be used in *in vitro* assays. The method does not require the cells are human as in Group III. The cells in Group III are not required to suppress the pathological immune response in a patient as in Group II. The method of using genetically modified cells does not require the genetically modified cells and the genetically modified cells do not require the method of using genetically modified cells.

Groups II and IV are patentably distinct because the purpose of Group II is to treat disease while the purpose of Group IV is to produce non-genetically modified human immunoregulatory T-cells. The protocols and reagents for treating disease and for producing T-cells are materially distinct and separate. The method of treating disease does not require the method of producing T-cells and the method of producing T-cells does not require the method of treating disease.

Groups II and V are patentably distinct because the purpose of Group II is to treat disease while the purpose of Group V is to produce genetically modified human immunoregulatory T-cells. The protocols and reagents for treating disease and for producing T-cells are materially distinct and separate. The method of treating disease does not require the method of producing T-cells and the method of producing T-cells does not require the method of treating disease.

Groups III and IV are patentably distinct because the composition of Group III can be used in *in vitro* assays while the method of Group IV is to used produce non-genetically modified human immunoregulatory T-cells. The composition of Group III does not have to be used in the method of Group IV and the method of Group IV does not require the composition of Group III.

Groups III and V are patentably distinct because the composition of Group III can be used in *in vitro* assays while the method of Group V is to used produce non-genetically modified human immunoregulatory T-cells. The composition of Group III does not have to be used in the method of Group V and the method of Group V does not require the composition of Group III.

Groups IV and V are patentably distinct because the methods result in cells having different structures and functions. The method of Group IV results in activated immunoregulatory T-cells while the method of Group V results in activated immunoregulatory T-cells expressing an exogenous protein. The protocols and reagents required for genetically modifying T-cells is materially distinct and separate from those required for merely isolating T-cells. The method of producing non-genetically modified T-cells does not require the method of producing genetically modified T-cells and the method of producing genetically modified T-cells does not require the method of producing non-genetically modified T-cells.

Claims 1-14 and 16 are generic to groups I and II.

Claim 18 is generic to Groups IV and V.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for Group I-V are different, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-0120.

Questions of formal matters can be directed to the patent analyst, Dianiece Jacobs, who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-3388.

Questions of a general nature relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

If attempts to reach the examiner, patent analyst or Group receptionist are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051.

The official fax number for this Group is (703) 308-4242.

Michael C. Wilson

MICHAEL WILSON
PRIMARY EXAMINER